UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,211	07/28/2003	Nyomi V. Yam	AZ0020USANP	5309

27777 7590 10/05/2006

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
WEBMAN, EDWARD J	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,211	YAM ET AL.	
	Examiner	Art Unit	
	Edward J. Webman	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-71* is/are pending in the application.

4a) Of the above claim(s) *50-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *63-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 50-62, drawn to a method of use, classified in class 514, subclass 258.

II. Claims 63-71, drawn to a composition, classified in class 424, subclass 473.

The inventions are independent or distinct, each from the other because:

Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process for using the product can be practiced with another materially different product such as the antipsychotic benperidol.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with H. B. Woodrow on 9/29/06 a provisional election was made without traverse to prosecute the invention of Group II, claims 63-71. Affirmation of this election must be made by applicant in replying to this Office action. Claims 50-62 are

withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 67-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 67-69 "amount" with the recitation of a number at the end of the claims is indefinite. Do applicants intend a ratio?

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 63-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lam et al (US 6,930,129) in view of PCT/EP00/02620 (equivalent US 6,667,060) and Cruz et al (US 6,706,282).

Lam et al teach a dosage form providing an ascending release rate (abstract). A capsule shape is disclosed (Figure 1 and column 4 line 54). An oral osmotic dosage form is specified (column 4 lines 31-32). Bi- and tri-layer tablet cores are specified (column 4 line 35). The bi-layer comprises a first layer containing a drug and a second push layer containing a fluid-expandable osmopolymer. A semipermeable membrane and an orifice are specified (column 4

lines 41-55). A tri-layer tablet is disclosed containing a first and second drug- containing layer (column 4 line 66-column 5 line 8). An osmagent in the push layer is specified (column 13 lines 6-7). At least 35% of an osmagent such as sodium chloride is disclosed (column 11 lines 36-39). A higher concentration of drug in the second layer of the tri-layer is specified (column 17 lines 28-32). Sorbitol in the first layer is disclosed (column 11 lines 42-44). 25.4% sorbitol is speicified (column 15 line 22). Antipsychotics are disclosed (column 5 line 40).

Cruz et al teaches a dosage form comprising push layer and a drug layer, a semipermiable wall, and an exit orifice (column 6 lines 25-42). A secondary wall, a subcoat surrounded by the semipermeable wall, which facilitates release of the drug, is disclosed (column 12 line 35-column 46). Hydroxypropyl celluloses of molecular weight 80-850K are specified (column 13 lines 11-13). Sorbitol and sodium chloride are specified as osmagents (column 11 lines 51-60).

Vandecruys et al teach 9-hydroxyrisperidone (paliperidone) as an antipsychotic (column 6 lines 39 and 42). A tablet is disclosed (column 16 line 37).

It would have been obvious to one of ordinary skill to add 9-hydroxyrisperidone to the composition of Lam et al to achieve the beneficial effect of an antipsychotic, and further to add a subcoat to the Lam et al vehicle to achieve the beneficial effect of facilitating release of the drug. As to claimed ratios of active in the first layer and second layer, Lam et al teach an amount of drug in the first layer higher than that in the second layer. An optimum suitable ratio may be obtained by routine experimentation. As to the claimed sodium chloride in the first layer, Cruz et al teaches the equivalence of sodium choride and sorbitol as osmagents.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 63-71 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34-35, 37-41 of copending Application No. 11/051165. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the scope of the claims of '165 regarding the shape of the dosage form.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500